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Food Safety And Inspection Service
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AUDIT REPORT FOR BELGIUM
MAY 16 THROUGH MAY 26, 2000

May 18,2001

INTRODUCTION

Purpose

This report reflects information that was obtained during the annual audit of Belgium's meat inspection system from May 16 through May 26, 2000, by a team of specialists from the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA).

Last Audit

The last audit of Belgium's meat inspection system was conducted in March 1999. Belgium's residue testing laboratory at the University of Ghent, Faculty of Veterinary Medicine, and the nine establishments (6, 45, 75, 93, 93-1, 135, 156, 227, 477) that were then eligible to export meat products to the United States were audited and found to be acceptable. One establishment (93) had minor deficiencies and was found acceptable subject to re-review in the next audit. Several equivalence issues were noted regarding HACCP and SSOP implementation, microbiological testing, and inspection system control as a result of the 1999 audit. Principal concerns with the system at that time were the following:

- In establishment 93-1, ceilings in the production area showed build up of dust and dirt; the floor was broken in several areas in the production area and metal crates covered with dust were being used for storage of packaged products.
- In establishment B-75, chemicals and food ingredients were not segregated in the dry storage area and packaging materials were stored in contact with the wall.
- In establishment B-227, the floor was broken in places within the production area, creating unhygienic conditions, and packaging materials were stored in contact with the wall in the dry storage room.
- SSOP procedures in establishments EEG-93 and CEE-135 did not address operational sanitation and did not produce any monitoring records.

Belgium authorities assured FSIS that corrective measures would be taken.

Export History

During calendar year 1999, Belgium exported 7, 886,748 pounds of canned pork products and other processed pork products to the United States. Port-of-entry rejections included 12,786 pounds for transportation damage. During calendar year 2000 from January to April,

Belgium exported 4,084,421 pounds of canned hams, picnic hams, and cured pork products to the United States. Port-of-entry rejections were 4, 837 pounds for transportation damage. Eighty-eight pounds from establishment 156 were rejected for unsound condition.

PROTOCOL

Belgian inspection system effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP's), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. The Belgian inspection system was assessed by evaluating these five risk areas. The 2000 audit was conducted in three parts.

Inspection Program Audits involved visits with Belgian national meat inspection officials to discuss oversight programs and practices, including enforcement and compliance activities. This was followed by on site audits of the eight U. S.-certified establishments and an onsite visit to a central laboratory culturing field samples for the presence of microbiological contamination with *Salmonella* and *Escherichia coli.* The Belgian government uses the University of Ghent laboratories for microbiological testing.

Residue Program Audits entailed audits by FSIS residue specialists of the National Residue Program and residue testing records in the meat inspection headquarters of the Institute for Veterinary Inspection.

Laboratory Program Audits involved a laboratory audit by FSIS chemists and Quality Control Specialists. Three laboratories were visited: The National Reference laboratory, the University of Gent laboratory, and the Ministry of Agriculture laboratory.

This report is organized in three parts to reflect findings in each area of interest.

SUMMARY OF FINDINGS

Inspection Program Audits

these were slaughter establishments; six were conducting processing operations. Based on performance of the individual establishments, Belgium's "In-Plant Inspection System

In-Plant System Controls In Place.

Effective controls were in place at five establishments and they were judged (06, 45, 135,156, 477). Two establishments (93 and 93-1) were judged to be and one establishment (B-75) was judged on the next audit. Establishment B-75 corrected its deficiencies in the dry storage area, however, other

The two *Unacceptable*
Details of audit findings and observations, including compliance with HACCP, SSOP's, and testing programs for and generic *E. coli*

Belgian inspection system officials are not conducting monthly supervisory visits to U.S. certified establishments.

Design of the Belgian residue program is consistent with Council Directive 96/23 in that it provides a focused, targeted approach for detecting the use of prohibited growth promotants.

compounds and to prevent violative residues in food products.

There does not appear to be a systematic approach or criteria for changing the focus

program. The decision to leave compounds in the program indefinitely limits the ability to expand the program to include new drugs, although there is a very active (research-based)

producing animals.

As a result of the 1999 PCB/Dioxin crisis, the 2000 residue plan was expanded to include

was developed to monitor feedstuffs for food-producing animals to provide trace back information and capability if a violation occurs. In addition, a new violation status (C-status)

Belgium's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Belgium inspection system had adequate controls in place to ensure compliance with

Laboratory Program Audits

Three Belgian laboratories were reviewed during a three and a half-day period, with varying degrees of intensity. All three laboratories were accredited by BELTEST (Ministry of Economic Affairs) following EN-45001 for the methods they utilize. The methods for which they have been accredited varied. In concert with the philosophy of the EC, not only were muscle, kidney, liver and fat samples analyzed, but the laboratories often analyzed matrices such as urine, feces and feedstuffs.

The Quality Assurance (QA) systems of the three laboratories were similar in overall philosophy; each had individual variations in how guidance had been implemented. All laboratories had a QA Manual with specific analytical procedures (methods) incorporated into Standard Operating Procedures (SOPs).

Several deviations from the SOPs were found in the two laboratories audited in greater detail. In addition, a small number of actions were observed that were not covered by SOPs. The defects, or omissions in documented cannot be considered to imperil or undermine the confidence in the laboratory testing results. The laboratories appeared agreed to make changes to their SOPs to cover these actions.

None of the three laboratories has written guidelines (or SOPs) for qualifying a new analyst to demonstrate "readiness to perform" for new analysts. The informal procedures, used as described, are reasonable but they should be written into the SOPs.

All three laboratories used methods validated under current EU guidelines (93/256/EEC). None of the laboratories used methods validated under the proposed guidelines.

ENTRANCE MEETING

On May 15, 2000, an entrance meeting with Belgian government officials was held at the Brussels offices of the Institute for Veterinary Inspection, Ministry of Public Health (IVK-IEV-MPH). This meeting was coordinated by Dr. Marc Cornelis, Director, Veterinary Policy, MPH. Also attending were Dr. Jos Clysters, Director, Residue Investigation Group; Dr. L. Lengele, Director, Veterinary Services, Animal Health, Ministry of Agriculture; and Dr. Andre Ermens; Dr. Guido Seurinck; Dr. Walter Smedts; Dr. Nelly Vermeeren; and Dr. An Sevenants, Veterinary Staff Officers, Animal Health, Ministry of Agriculture.

The U.S. delegation was led by Mr. Donald Smart, Director, Review Staff and Dr. Suresh Singh, Lead Auditor, Food Safety and Inspection Service (FSIS). Also attending from FSIS were Dr. Michael Hoffman, Chemist; Ms. Rita Kishore, Chemist; Ms. Mary Stanley, Food Technologist; Mr. Terry Dutko, Quality Assurance Officer, Midwestern Lab; Mr. Joel Salinsky, Quality Assurance Officer, Eastern Lab; Dr. Manzoor Chaudry, Residue Chief, Slaughter Operation Staff, TSC. Dr. Elizabeth Leovey, Chemist, Environmental Protection Agency (EPA), who was on detail for this audit, also attended. Mr. Philip Letarte, Agriculture Counselor, and Ms. Marie France Rogge, Agriculture Assistant, represented the U.S. Embassy.

Topics of discussion included the following:

- Welcome by MPH-Belgium and explanation of the Belgian meat inspection system.
- Overview of the National Residue Program database.
- Discussion of the previous audit report and team audit concept.

Subsequent to that meeting, the USDA team divided into three subgroups and pursued their individual audit goals.

INSPECTION PROGRAM AUDIT

Purpose

The purpose of this portion of the audit was to evaluate Belgian inspection system controls over establishments certified for export to the United States.

Method and Scope

This audit consisted of establishment record reviews and on-site visits to selected establishments.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of the Belgium inspection system in March 1999. To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the Veterinary inspection officials who normally conduct monthly supervisory reviews and/or audits for compliance with U.S. import requirements lead the audits of the individual establishments. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Inspection visits to establishments that were certified for export to the U.S.
- Training records for inspectors
- Records such as generic labels and animal raising claims
- New system implementation documents such as laws, regulations, notices, directives and policy guidelines
- Sampling and laboratory analyses for residues

- Pathogen reduction and other food safety initiatives such as SSOP's, HACCP programs generic *E. coli* testing and *Salmonella* testing
- Sanitation, slaughter and processing inspection procedures and standards
- Control of products from livestock with conditions such as tuberculosis and cysticercosis, control of inedible and condemned materials, and veterinary coverage
- Export product inspection and control including export certificates
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, and seizures; control of noncompliant product; and withholding, suspending, or withdrawing inspection from certified establishments that export to the United States

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection service veterinarians and inspectors in establishments certified by Belgium as eligible to export meat products to the United States were full-time Institute for Veterinary Inspection (IVK-IEV) employees of the Ministry of Public Health, receiving no remuneration from either industry or establishments.

Establishment Audits

During the on-site establishment visits, FSIS evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. Auditors also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered *Unacceptable* and are ineligible to export products to the United States.

At the time this audit was conducted, eight establishments were certified by Belgium to export meat products to the United States. All eight were visited for on-site audits. In five of these establishments (06, 45, 135, 156 and 477), both Belgium inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. These five establishments were found *Acceptable.* One establishment (75) was rated *Acceptable Subject to Re-review* on the next audit because of several deficiencies regarding sanitation and the condition of facilities. Two establishments (93 and 93-1) were rated *Unacceptable* because of major contamination and sanitation problems, which are mentioned later in this report.

Microbiology Laboratory Audits

Belgium's microbiological testing program for *Salmonella* and *E. coli* was being performed in the government laboratory at the Faculty of Veterinary Medicine, Veterinary Food Inspection, at the University of Ghent, Merelbeke. Dr. J. Van Hoof is the Head of Department at this Laboratory. The Belgian microbiology testing system met the criteria established for the use of laboratories under FSIS's Pathogen Reduction/HACCP rule. The

laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities. Results of analyses were being reported to the inspection authorities of the government and the establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the eight establishments audited:

Swine slaughter, cutting, and boning—three establishments (93, 93-1, and 135)
Pork boning and canning—two establishments (06 and156)
Chicken, pork and beef cooking for ready-to-eat meals—one establishment (477).
Pork, cutting, boning and curing and cooking—two establishments (45 and 75).

Sanitation Controls

Based on the on-site audits of establishments, Belgium's inspection system had controls in place for water potability, hand washing facilities, sanitizers, pest control programs, temperature control, lighting, and ventilation. Establishment construction, condition of facilities and equipment, product protection and handling, and establishment sanitation programs were acceptable except in establishments 93, 93-1 and 75. In establishments 93 and 93-1, the floor, overhead structures and conveyor belts were in need of repair and replacement and there was a lack of a maintenance program in establishments. Direct product contamination was observed in both establishments. In establishment 75, flaking paint on the walls and ceiling, cracked floors, rust on the overhead structures, and an ineffective maintenance program were observed.

Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if FSIS requirements for SSOP were being met in an equivalent manner. The data collection instrument used accompanies this report as Appendix A.

The SSOP were found to meet the basic FSIS requirements except in establishments 93, 93-1 and 75 where corrective actions were not being taken for contamination of product-contact surfaces; and operational sanitation checks were not being recorded.

Cross-Contamination

Water and condensation drip contamination were observed on pork cuts in establishment 93-1. The cutting line was not stopped immediately and Belgian inspection officials took no corrective action until the FSIS auditor pointed out the condition. The line was then stopped for temporary disinfecting with alcohol.

The conveyor belt in the boning room of the establishment 93-1 was broken in several places, had large holes, and was torn on the edges making it unhygienic and hard to clean.

Inspection and establishment officials discussed this problem and it was agreed to replace the belt.

Peeling paint and rust spots were observed in the cooler in the establishment 75. Inspection and establishment officials discussed this issue and agreed that corrective action would be taken.

Product Handling and Storage

Cooked and raw meat products (casings) and bread were stored in the same cooler in establishment 75. Reconditioning of products from the floor was not done properly and there were no specific reconditioning procedures in establishments 93-1 and 75. Boneless meat re-inspection program is not carried out as required in establishment B-45. No records were maintained by Quality Control regarding defects in de-boned meat on a daily basis.

Personnel Hygiene and Practices

In all establishments, employees were observed to follow good personal hygiene practices.

Animal Disease Controls

Belgium's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

Residue Controls

Please see the attached Residue Program Audits Section.

Slaughter/Processing Controls

All establishments approved to export meat products to the U.S. are required to develop and implement a Hazard Analysis and Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report as Appendix B.

HACCP Implementation

The HACCP programs were found to meet FSIS regulatory requirements.

Testing for Generic *E. coli*

E. coli and *Salmonella* testing are not required in Belgian slaughter establishments that are certified to export meat products to the United States. Animal and Plant Health Inspection Service regulations prohibit the importation of meat from hogs slaughtered in Belgium because of animal disease concerns. Belgium obtains meat for its products that are exported to the U.S. from hogs slaughtered in a third countries that are eligible for export to the United States.

However, Belgian swine slaughter establishments were testing for generic *E. coli* and *Salmonella* for their own monitoring of process control procedures.

Inspection System Controls

Inspection system inspection controls include (1) ante-and post-mortem inspection procedures and dispositions, (2) control of restricted product and inspection samples, (3) control and disposition of dead, dying, diseased or disabled animals, (4) boneless meat re-inspection, (5) shipment security, including shipment between establishments, (6) prevention of commingling of product intended for export to the United States with domestic product, (7) monitoring and verification of establishment programs and controls including the taking and documentation of corrective actions under HACCP plans, (8) inspection supervision and documentation, (9) the importation of only eligible livestock or poultry from other countries, i.e., only from eligible third countries and certified establishments within those countries, and (10) the importation of only eligible meat or poultry products from other counties for further processing. These controls were in place for all establishments audited with the exception of establishments 93, 93-1, and 75.

Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Species Verification Testing

At the time of this audit, Belgium was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

The Kring Director performs in-depth reviews of U. S. certified establishments once or twice a year. Local Veterinarians of MPH were conducting reviews based on the time available to them and reviews. These reviews were not done routinely on a monthly basis.

The internal review program was not applied equally to both export and non-export establishments. The records of audited establishments were kept in the inspection offices of the individual establishment and in the Kring (regional) MPH offices.

Enforcement Activities

Enforcement activities are carried out by MPH, which has full power to initiate all enforcement actions.

RESIDUE PROGRAM AUDITS

Purpose

To purpose of this audit activity was to evaluate the effectiveness of Belgium's residue control program for meat and poultry products.

Method and Scope

The residue review subgroup was composed of three FSIS employees from the Office of Policy, Program Development and Evaluation, Office of Public Health and Science and Office of Field Operations. The subgroup met with Belgium officials from the Ministry of Public Health, Institute of Veterinary Inspection (IEV) and the Ministry of Agriculture, General Administration for animal health and the quality of animal products (DGV). The purpose of this meeting was to obtain background information from the appropriate competent authority regarding organization, roles and responsibilities and an overview of the residue control program.

During the remainder of the week, the residue review subgroup conducted site visits to a pork slaughter establishment, a swine farm, and to the State Police headquarters. During all visits, a representative from the appropriate office accompanied the residue review subgroup.

Belgian Residue Program

The primary objective of the Belgian residue control program is to provide an effective and uniform monitoring system to detect the presence of chemical residues in live animals, feed components and meat products. A targeted sampling approach is applied with regard to the use of illegal substances in animals, while surveillance sampling is aimed at verifying compliance with the maximum residue limits (MRL) of approved veterinary medicinal products and other contaminants in foodstuffs of animal origin. The appropriate authorities collect specified tissues, which are analyzed at designated laboratories. Tissue samples, such as the muscle around injection sites, are also collected from suspect animals or carcasses at the discretion of the inspector. The causes of residues in food of animal origin are investigated, as well as sampling increased to assure detection of additional non-compliant products and to deter future misuse.

Organization

Responsibility for the residue control program is shared between the Ministry of Public Health and the Ministry of Agriculture.

Ministry of Public Health

The IEV is designated as the central coordination organization for monitoring and controlling residues in food products of animal origin, in accordance with European Community legislation. IEV has specific responsibilities for developing Belgian legislation and program instructions on the residue program, including sampling at slaughter establishments and for analyses at designated laboratories. Oversight at the laboratories includes accreditation, analyses techniques, sample treatment procedures and distribution of the results. IEV is comprised of a central administration, two districts with National competence and 6 units with regional competence.

Ministry of Agriculture

DG V is responsible for animal identification, animal welfare and movement between farms/slaughter establishments, sampling of tissues from the live animals on the farm and the application of the R- and H-statute (see enforcement action). The General Administration for the quality of raw material and the plant sector (DG IV) is responsible for sampling animal feeds. Each of these General Inspectorates is comprised of a central administration as well as a regional administration.

Ministry of Health

The General Pharmaceutical Inspectorate is responsible for evaluating the quality, safety and efficacy of animal health products. Animal health products cannot be marketed without authorization. Pharmacists distribute these products through wholesale distributors for use by veterinarians that are treating specific cases. (Note: the residue review subgroup did not meet with or discuss the drug approval process in Belgium.)

Interdepartmental Residue Cell (CIR)

Through the Central Bureau of Research in Brussels, the Multidisciplinary Division Hormones coordinates various investigations to trace back the use of illegal substances, gather intelligence and control active cases throughout Belgium. This enables unified action against residue violations, with special emphasis being placed on hormonal crime. Weekly meetings are held among six ministries: Agriculture Veterinary (DG IV and V), Public Health (IEV), General Pharmaceutical Inspectorate, Justice (Public Prosecutors), Finance (Customs), and Interior (State Police/National Hormone Cell).

Legal Authority

National legislation of both the Ministry of Public Health and the Ministry of Agriculture is based on European Community legislation related to the ban of hormonal substances (Council Directive 96/22/EC) and the control of residues in live animals and animal products (Council Directive 96/23/EC). These directives were transposed into Belgium law through the law of July 15, 1985, amended by the law March 17, 1997, the Royal Decrees of September 8, 1997 and October 11, 1997 and the Ministerial Decree of September 10, 1997.

Regarding approval and use of animal health products, EU Regulation 2377/90/EC lists drugs permitted for therapeutic use in each species of food animal, and establishes MRL's per species per matrix. This regulation also lists products not requiring an MRL, products for which a temporary MRL has been established, and a list of products banned for the use in livestock. In reference to this EC regulation and Belgium law of March 28, 1975, the Royal Decree of September 8, 1997, and the Ministerial Decree of September 10, 1997 have been passed. This legislation authorizes officials of the Ministry of Agriculture to apply an R- or H-statute to companies, depending on whether the violation results from the use of approved or banned material. It also provides for written notification if the withholding period had not been honored for the drug administered prior to transporting the animal to another location.

The Royal Decree of June 29, 1999 (Ministry of Health) provides for the "extra label use of materials," which are to be issued by pharmacists. The minimum withholding period is 28 days for animals intended for slaughter.

Residue Plan Design, Review and Approval

The Ministry of Public Health (IEV) and the Ministry of Animal Health (DG IV and V) meet with laboratory experts to decide which compounds are to be included in each group of substances outlined in Council Directive 96/23/EEC. Belgium relies on guidance from the Commission, as well as method availability when expanding the list of compounds. However, once a compound is included in the plan, it remains there indefinitely since there are no provisions to remove it. It was also confirmed that multiple laboratory analyses are performed on a sample to efficiently fulfill compliance to the plan.

Since 1998, seven compounds have been added to the residue plan (Table 1). Four of these compounds are Group A substances (Substances with Anabolic Effects or Non-authorized) and three are from Group B (Veterinary Drugs and Environmental Contaminants).

Table 1: Compounds added to the Belgium residue program since 1998

GROUP	COMPOUNDS	1998	1999	2000
A3 Steroids	16 OH Stanozolol	-	-	X
	Flugeston acetate	-	X	X
	Triamcinolone	-	X	X
	Methylprednisolone	-	X	X
A5 ∃-agonists	Clenproperol	-	X	X
B2a Anthelmintics	Ivermectin	-	X	X
B3a Organochlorides	Dioxin	-	-	X

There were no established guidelines or criteria available to support the inclusion of additional compounds into the plan. In the case of newly approved substances being considered for the plan, IEV indicated that testing is done for all approved compounds with

established MRL's. However, this is neither feasible nor realistic and is not being done. As an example, in Group B2a (anthelmintics) Belgium targets benzimidazoles (including febentel, fenbendazole, and oxfendazole) and ivermectin in its red meat 2000 residue plan, but does not include doramectin and moxidectin, which are approved substances listed in Council Regulation 2377/90 (amended). In addition, flunixin (a non-steroidal anti-inflammatory drug (NSAID)) is a drug approved for use in swine in Europe (MRL = 50 :g/kg in muscle). However, flunixin is not approved for use in swine in the United States, which impacts the accepted tolerance for detectable residues. Since this drug is not included in the Belgian residue plan, there would be no assurances that there are no detectable residues present in pork.

In the case of prohibited substances, illegal drugs or mixture of drugs ("cocktails") that are seized by the police are submitted to the laboratories for identification. Once a method is developed and after a favorable opinion from the NRL, the compound is included in the plan. For example, the illegal use of 16 hydroxy (OH) stanozolol was confirmed through surveillance activities, and in July 1999, the compound was immediately added to the 1999 residue plan.

Sampling frequency is based on the previous year's production data, which is not available at the time the plan is developed. Therefore, the production data used to generate the sampling frequency must be estimated. IEV indicated that they overestimate this level of production so the targeted sampling frequencies may exceed the actual samples collected.

Consistent with EU legislation, Belgium uses a targeted approach to all residue sampling, applying the specified levels and frequencies from Directive 96/23/EEC. In addition, Belgian authorities consider results from previous years and adjustments are made to the sampling and analysis frequency. However, there are no set criteria for increasing the sampling number based on violations. Further, the increase in targeted sampling is not evidenced during implementation.

As an example, sampling of swine for tranquilizers (Group B2d) at slaughter was increased in 1999 and 2000 due to evidence that hogs were being sedated for transport. Reported 1999 results indicate that only 101 targeted samples were analyzed for swine in Group B2d (see Appendix C). This may be the result of production overestimation when developing the plan or perhaps a failure to collect samples that are scheduled. As another example, sampling of cattle, swine and poultry was increased at slaughter as a result of the dioxin crisis in 1999. It should be noted that in the case of PCBs, Belgium applies a statistical approach to sampling (300 samples per each species) in order to establish a confidence level for detection of the substance.

Planning was completed in December 1999 so that it could be submitted to the EC for subsequent review and approval as well to meet the implementation schedule beginning in January 2000. Results of the EC review had not been received at the time of the audit.

Residue Plan Operations

On-farm Activities

Animal Identification. The Belgium identification and registration system for farm animals (SANITEL) is the responsibility of the Ministry of Agriculture (DG V). Each farm (producer) is required to register and is responsible for identifying animals in accordance with requirements for the species. In the case of bovine, each individual animal is identified within a week of birth with two plastic eartags with the same number (lifelong) and is issued a "passport" which must accompany the animal during transport. Swine are identified before the age of weaning with one plastic eartag with the landcode, a code (stockfarm or federation), and a serial number and for transport as a group using a shortened farm code.

This registration is entered into the provincial computer database, which is connected at a National level. The database maintains a complete history of producer activities relating to animal production, and provides a means to track the movement of animals between farms, out of the country or to slaughter. If necessary, trace back to the farm of origin is possible.

Sample Selection, Identification and Security. The sample request control plan is generated centrally and provided to inspectors in the field weekly. Inspectors make unannounced visits to the farm, collecting blood, urine and feces samples from 6 cattle or10 swine. A different team of inspectors from DG IV collects samples of feed from bulk bins and feed troughs. All samples are sealed and transported with appropriate paperwork to the designated laboratory. These samples are usually delivered in person.

Slaughter Establishment Activities

Sample Selection, Identification, and Security. Three types of samples are collected at slaughter establishments: monitoring, intensified (R- or H-statute), and suspect. Though government inspection personnel perform no in-plant testing, plant management does use an ELISA test for sulfa-drugs.

The monitoring sample request control plan is generated centrally by IEV and is provided to the teams of inspectors that are responsible for collecting residue samples. The plans for Group A compounds (hormone and prohibited substances) are generated monthly, while the remainder of the plan is generated on a weekly basis. There are six teams of inspectors distributed in each of the six districts (4 teams in the Flanders region and 2 in the French region.) Sample selections are at discretion of the residue collection team and are targeted especially for Group A substances. Samples are then placed in plastic containers and tamper-evident sealed. Each set of samples is identified with a pre-printed tag following established procedures. Samples are stored in containers with dry ice and are delivered to the designated laboratory, usually by the inspection team. Otherwise, taxi services are utilized.

Intensified samples are collected from lots of animals designated in the R- or H-status. Documents arriving at the slaughter establishment identify this status. The residue sample collection team collects samples, if present. Otherwise, the on site inspector collects the

samples from 10 % of the animals presented. In addition, any time animals are suspected of having been treated with illegal or prohibited substances or if injection sites are noticed, tissue samples are collected and analyzed for all Group A substances.

Reporting Positive Results

Reports issued by the laboratories are provided to IEV, which notifies other Ministries of the violations. Immediate action is initiated, depending upon the group of substances.

Enforcement Action

R-Statute

When a violation occurs for an authorized substance (Group B), sampling is intensified at the slaughter establishment. All vignettes (passports or transportation documents) are modified to reflect the R-status (for residues), which triggers additional sampling for the next 8 weeks. After this time period, vignettes are reissued without the R-status. All increased sampling is done at the expense of the producer.

H-Statute

When a violation occurs for an illegal or prohibited substance (Group A), the H-Statute is applied (for hormones). Application of this statute triggers additional sampling at the farm and 10% of animals are sampled. If one animal is found to be positive, all animals are sampled. Each animal testing positive is subsequently destroyed. In addition, the passports are modified to reflect the H-statute.

When a violation at the farm or at the slaughter establishment occurs for an illegal or prohibited substance (Group A), the H-Statute applies, which triggers the additional sampling of 10% of the animals at the slaughter establishment for 52 weeks. This intensified sampling is at the expense of the producer.

When a new violation for an illegal or prohibited substance is found within this period, the period is extended for 104 weeks.

State Police. As part of the Multidisciplinary Division Hormones, the State Police provide enhanced controls and logistical support to investigations that follow all H-statute violations. Local units accompany Ministry of Agriculture inspectors onto the farm to collect additional samples or to take action on animals that have had positive findings. The intermediate and central offices organize specialized investigations and gather intelligence to provide evidence necessary for prosecution.

The State Police lead efforts to repress and prevent abuse of prohibited substances, which are sustained by weekly meetings between the Ministries. This weekly direct communication facilitates discussion of new and current files on active investigations of violations, and enables a unified plan for controls on farms and at slaughter establishments. This exchange

is further enhanced by an exchange of information between the different services. The overall strategy, along with improvements evidenced by judicial actions taken against violators (farmers, distributors, illegal laboratories producing the mixtures, and pharmaceutical companies providing the base materials) are reported annually, evidencing a coordinated approach against the use of hormones.

Findings and Recommendations

Organization and Legal Authority

A positive relationship between the Ministry of Agriculture and Ministry of Public Health, as well as other Ministries and Departments was evidenced by open communications when addressing problems associated with a breakdown in residue controls.

Residue Plan Design

Design of the residue program is consistent with Council Directive 96/23, supporting a focused, targeted approach for detecting the use of prohibited growth promotants. Belgium's residue program relies primarily on testing to deter the use of illegal compounds and to prevent violative residues in food products. In spite of all these efforts, there continues to be an alarming rate of violations of prohibited substances.

There is no apparent systematic approach, rationale, or criteria for selecting veterinary drugs or other compounds to be included in the national residue control program. The decision to leave compounds in the program indefinitely limits the ability of Belgium to expand its program to include new drugs.

There is an overall lack of awareness of new drug approvals with in the European Community and the relationship to U.S. drug approvals. As an example: Flunixin was on the shelf at the swine farm visited. This drug is approved for use in cattle and swine in Europe and was properly dispensed at the farm. However, flunixin is not approved for use in swine in the U.S. so there should be no detectable levels of the drug in edible tissue if used outside the scope of the approval.

The residue control program does not schedule residue testing of imported products (from third countries or member states), though random monitoring samples are collected on products imported into Belgium. Since imported product is currently used in product prepared and exported to the United States, there should be assurances that the product complies with U.S. tolerances.

Residue Plan Operations

Inspectors visiting farms to collect samples also use this opportunity to educate the farmer on proper use of compounds.

Internal controls monitoring weekly sample request forms were insufficient. Samples collected at the slaughter establishment were incorrectly identified as week 12, rather than week 20.

Samples collected at the slaughter establishment during the year were significantly fewer than what was planned for the year (example: In 1999, 110 out of 400 targeted pork samples were collected and analyzed for tranquilizers).

Enforcement

The Belgian animal identification system is effective in enabling trace back of a violative animal from a slaughter establishment to the farm of origin.

Producers are able to avoid the penalty associated with the R- and H-Statute by diverting animals under another name or not presenting animals for slaughter during the penalty phase.

Budgetary constraints and reallocation of staff may limit the effectiveness of enforcement activities. During the audit, six of the nine State Police inspectors had been detailed to cover the soccer games.

As a result of the 1999 PCB/Dioxin crisis, the 2000 residue plan was expanded to include Dioxin testing. In addition, the Contaminants Surveillance Monitoring System (CONSUM) was developed, which is designed to monitor feedstuffs, farms, food consumed by humans and to provide trace back if a violation occurs. In addition, a new statute (C-statute) has been added, which will intensify sampling as a result of a violation.

LABORATORY PROGRAM AUDITS

Purpose

The purpose of this portion of the audit was to evaluate the effectiveness of the laboratory aspects of the Belgium residue control program for meat and poultry products.

Method and Scope

The laboratory review subgroup (LRS), composed of three employees from the Office of Public Health and Science, Food Safety and Inspection Service and one employee from the Environmental Protection Agency, was one part of three-part USDA team that audited the Belgian Residue Control System.

The LRS conducted sites visits/audits at three laboratory facilities: The National Reference Laboratory (located in Brussels); the Laboratory of Chemical Analysis, University of Gent, Faculty of Veterinary Medicine under the direction of Professor Dr. Hubert De Brabander; and a State Analysis Laboratory, Ministry of Small Enterprises, Traders, and Agriculture under the direction of Dr. Dirk Courtheyn, also located in Gent. During all laboratory visits, Dr. Marc Cornelis, Director of the Ministry of Public Health, Institute of Veterinary Inspection, accompanied the subgroup.

The analytical capability and capacity of the National Reference Laboratory (NRL) is supplemented by the capability of six additional laboratories operating under contract to either the Ministry of Public Health or under auspices of the Ministry of Agriculture, or both. These are often Government or University-based laboratories. The laboratory analysis system for residues is very well funded. The Ministry of Health budget for the analysis of meat and poultry at the NRL and the contract laboratories is approximately 132M Belgian francs ($8M USD). The Ministry of Agriculture provides additional funds for residue analysis.

Overall laboratory system capability enables analyses to be conducted for illegal substances in food animals plus a monitoring program that verifies compliance with European Union (EU) maximum residue limits (MRL) of approved veterinary medicinal products, as well as analyses for environmental and other contaminants in animals and animal feeds. Reports issued by the laboratories are provided to IEV, which notifies other Ministries of the violations. Immediate action is initiated, depending upon the nature of the violation.[1]

[1] A PCB contamination of feedstuffs was uncovered while the auditors were in Belgium. This finding led to the immediate quarantine of the feedmill and several farms that were direct purchasers from the feed mill. Within two days, the quarantine expanded further, to prevent exposed animals from entering the food chain. The episode was well publicized by the Ministry of Public Health and other governmental bodies in the media through press conferences, etc. The USDA team was given a full briefing at the exit conference.

Findings

Three laboratories were reviewed during a three and a half-day period. (See Appendices C, D, and E.) The laboratory at the Veterinary Faculty, University of Gent was the most intensively reviewed. This review focused on the quality systems, sample custody, analysis, preparation of analytical standards and stock solutions, a GC-MS method and a LC-MS method. The review of the National Reference Laboratory (NRL) in Brussels focused on similar areas, but fewer than eight hours were available for this visit, so a less detailed review was possible. Time constraints also shortened the review of the Ministry of Agriculture's laboratory in Gent to less than a single afternoon. In that laboratory, our visit was limited to background information on laboratory activities and a tour of the work areas, following the path a sample would take from receipt through analysis to reporting of data to either the Ministry of Agriculture or the Ministry of Public Health.

All three laboratories were accredited by BELTEST (Ministry of Economic Affairs) following EN-45001. The methods for which they have been accredited varied. The Ministry of Agriculture laboratory was accredited for hormones, corticosteroids, Beta-agonists, other contaminants and PCBs, and often analyzed matrices such as urine, feces and feedstuffs.

The University of Gent laboratory was only accredited for qualitative analyses, though for those compounds with an MRL, the laboratory did have to make a judgement as to whether to send a sample to NRL for confirmation. That is, the laboratory primarily analyzed for prohibited compounds for which confirmation by mass spectrometry was required. They also analyzed for PCBs, with quantification (provided by internal standards) obtained concurrent with confirmation.

The Quality Assurance (QA) systems of the three laboratories were similar in overall philosophy. Each had individual variations in how guidance had been implemented. All had a QA Manual with specific procedures incorporated into Standard Operating Procedures (SOP's). While the method SOP's in the NRL included all of the procedures necessary to conduct a method and contained the validation data, the Ministry of Agriculture's laboratory in Gent used a modular approach to method SOP's. Each different phase of a method, i.e. extraction, clean-up, and analysis, were described in different SOP's. Some methods were similar in their extraction techniques and others in instrumentation. This modular approach reduced the amount of time needed to revise SOP's and to revalidate and recertify analysts and methods.

None of the three laboratories had written guidelines (or SOP's) for qualifying a new analyst to demonstrate "readiness to perform." The informal procedures used are reasonable as described, but they should be written into SOP's.

The level of documentation varied between laboratories. The two field laboratories appeared to maintain a level just necessary to retain their accreditation. Both were very careful to keep their costs down. (They are paid a predetermined amount for each sample analyzed.)

Each laboratory had a QC Coordinator. However, the Quality Assurance Coordinator was only available at the NRL. The University of Gent's coordinator worked part time, approximately two days a week. The NRL's Food Safety Section QA Coordinator was full time. The laboratories had a similar progression of procedures for reviewing data reports, i.e. analyst, program leader or senior analyst and finally the director of the unit. The raw data are first verified by a senior scientist and subsequently approved by the head of the program and the head of the section at the NRL. The Director of the Food Safety Section, NRL managed over forty employees. With such a large unit, there may be a question as to depth of the review.

The other two laboratories had smaller staffs. When a supervisor was not available, other staff were given signatory approval over final reports. With a limited number of staff, there were times in the University of Gent laboratory that only two levels of review were conducted. The QA Coordinators had no responsibility for data review, except during internal audits. It may be advisable for both of these small groups and for a very large group to include the QA Coordinator in data review and approval when a manager is not available to perform this function, or is unable to review it in enough depth to detect mistakes. The QA Coordinator could, for instance, review a subset of reported data (choosing one or two samples from a set) to assure that quality criteria were meet.

All three laboratories used methods validated under current EU guidelines (93/256/EEC). They did not use the proposed guidelines.

Conclusions

The laboratory analysis portion of the Belgian residue control system appears to be run in a competent and quick-reacting manner. The three laboratories that were audited each had a number of small "defects" but none of them appear to be problematic. The major defect within the three laboratories appears to be the lack of an SOP for qualifying new analysts to perform on-going methods within the laboratory. The reporting systems appear to be quite effective and follow-up action on violations appears to be quite efficient.

EXIT MEETINGS

Exit meetings were conducted in Brussels on May 19 and May 25, 2000. The first exit conference was arranged by MPH and was held at offices of the Institute for Veterinary Inspection. The Belgium participants were Dr. Marc Cornelis, Director, Animal Products; Dr. Luc Lengele, Director Animal Health; Dr. Roger Francaux, Acting Chief Veterinary Officer; Mr. Albert Vandersanden, Deputy Director, Investigation; and Drs. Nelly Vermeeren, Walter Smedts, Audle Ermens and Jos Clysters. Other participants were Ms. Marie France Rogge, Agriculture Assistant, American Embassy, Brussels; Mr. Donald Smart, Director, Review Staff; Dr. Suresh Singh, International Audit Staff Officer; Dr. Manzoor Chaudry, Branch Chief, Residue, Technical Service Center; Dr. Michael Hoffman, Branch Chief, Emerging Issues; Ms. Rita Kishore, Chemistry and Toxicology Division; Ms. Mary Stanley, Food Technologist, International Policy Division; Dr. Elizabeth Leovey, Chemist, Environmental Protection Agency; Mr. Terry Dutko, Quality Manager, Midwestern Laboratory; and Mr. Joel Salinsky, Quality Manager, Eastern Laboratory.

The following topics were discussed:

- Audit findings and conclusions of the Laboratory Program Subgroup.
- Audit findings and conclusions of the Residue Program Subgroup.
- Investigation procedures and criminal prosecution of illegal veterinary drug and feed additives use in Belgium.

A second exit meeting was held on May 25 at the Institute for Veterinary Inspection. The participants were Dr. Marc Cornelis, Director Animal Products; Dr. Roger Francaux, Acting Chief Veterinary Officer; Dr. Frank Swartenbroux, Veterinarian; and Dr. Nelly Vermeeren, International Relations of IVK-MPH. Dr. Suresh Singh, Lead Auditor, represented the United States.

The following topics were discussed:

- Findings and conclusions of the Inspection Program Subgroup.
- HACCP-preshipment verification and SSOP record keeping for pre-operational and operational sanitation.
- Boneless meat inspection program requirements.
- Supervision of inspection staff and verification of HACCP records.

CONCLUSIONS

The meat inspection system of Belgium was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Eight establishments were audited; six were acceptable and two were unacceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed. The unacceptable establishments were delisted by Belgian authorities. The Belgian residue laboratory and residue control programs were satisfactory.

Dr. Suresh P. Singh
Lead Auditor

(Signed)*Dr. Suresh P. Singh*

Appendices

A. Data Collection Instrument for SSOP
B. Data Collection Instrument for HACCP Programs
C. Audit of the National Reference Laboratory
D. Audit of the University of Gent Laboratory
E. Visit to the Ministry of Agriculture Laboratory
F. Belgian Response to the Draft Final Audit Report

Appendix A

Data Collection Instrument for SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the person responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written SSOP	2. Pre-op sanitation	3. Operation sanitation	4. Food contact	5. Task frequency	6. Person resp	7. Daily records	8. Dated and signed
06	√	√	√	√	√	√	√	√
45	√	√	√	√	√	√	√	√
75	√	√	No	√	√	√	No	√
93	√	√	No	√	√	√	No	√
93-1	√	√	No	√	√	√	No	√
135	√	√	√	√	√	√	√	√
156	√	√	√	√	√	√	√	√
477	√	√	√	√	√	√	√	√

Appendix B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCP's and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow chart	2. Haz anal	3. All haz id	4. Use id	5. Plan each haz	6. CCP all haz	7. Mon crit limits	8. Corr action	9. Plan val	10. Plan verify	11. Rec keep	12. Dated and signed
06	√	√	√	√	√	yes	yes	yes	yes	yes	yes	yes
545	√	√	√	√	√	√	√	√	√	√	yes	√
45	√	√	√	√	√	√	√	√	√	√	√	√
75	√	√	√	√	√	√	√	√	√	√	√	√
93	√	√	√	√	√	√	no	√	√	√	√	no
93-1	√	√	√	√	√	√	√	√	√	√	√	√
135	√	√	√	√	√	√	√	√	√	√	√	√
156	√	√	√	√	√	√	√	√	√	√	√	√
477	√	√	√	√	√	√	√	√	√	√	√	√

Appendix C

Audit of the National Reference Laboratory

Laboratory: NRL (Scientific Institute of Public Health – Louis Pasteur)
Director: J. M. Degroodt
Status: EN 45001 Accredited

The NRL Food Safety staff of approximately 45 included eight Ph.D. scientists, 13 scientists with the equivalent of Master's degrees, 16 technicians (4 years of formal study after high school graduation), 7 technical support (in-laboratory training after graduation from high school) and several administrative support personnel. The laboratory has a number of functions, ranging from research, methods development and serving as the expert laboratory in Belgium to performing regulatory analyses. The NRL was very well equipped in terms of instrumentation (gc/ ms; lc/ms/ms; hplc-pda; gf/aas), and is accredited by BELTEST to comply with EC directive 96/23 (anabolics, hormones, β-agonists, antibiotics, natural toxins, heavy metals, and pesticides). The laboratory has participated in approximately 20 certification studies and interlaboratory studies for veterinary drugs, pesticides and environmental contaminants since 1996. The NRL performs between 8000 and 9000 regulatory analyses per year.

The Laboratory had a comprehensive QA program and followed standard QA/QC practices. The QA Coordinator was interviewed. Of the three laboratories audited, the NRL appears to have the most comprehensive QA/QC program. The QA Manual was organized so that it can be easily amended. The Manual focused on principles and objectives while the SOP's detailed methods and procedures. SOP's were easily revised by amendments signed by the QA Coordinator and the head of the QA Bureau. The BELTEST accreditation was applied to routine testing while Good Laboratory Practices were applied to studies and drug and pesticide work. The analyses of interest were covered by the BELTEST accreditation.

The Food Safety Section's QA Coordinator reports to the Director of the Section. The Chief of NRL's QA Bureau apparently assessed his performed as a QA Coordinator. The amount of independence that the QA Coordinator has in resolving QA problems and reporting them to the NRL Director appeared to be limited, since he appeared to report to two individuals: the Director of the Food Safety Section and the Head of the QA Bureau. The laboratory was apparently cognizant of this apparent conflict since the Head of the QA Bureau did audit the Food Section and QA Coordinators from the other Sections or Departments would audit each other's organizations.

The QA Coordinator was a certified auditor not only for BELTEST but also for GLP's. He had been applying some of the principles of GLP's to enhance the Food Safety Section's QA System, and was trying to have some input into data quality. Method SOP's contained validation information to insure QA input into method acceptance. When the method validation SOP was initially developed, it specified a high and low standard for each set to determine whether the calibration curve had changed.

The SOP was amended later to require only one standard per set. The SOP did require that recoveries be monitored using control charts for routine accredited methods, and that the analysis be repeated if recoveries were unacceptable. Following common practice, an Excel-based control chart program was used to monitor recoveries and identify out of control trends.

The NRL audit program had some desirable features. Internal QA System audits were performed twice a year and deviations and corrective actions were documented. These audits assessed whether the QA system was functioning as described in a QA Manual and SOP's. The auditing SOP specified a yearly plan and contained an audit checklist. These audits appeared to be intensive and involved reviewing a couple of methods. Deviations or problems were noted in a form and classified into minor or major deviations. A minor deviation discussed in an audit report had to be resolved within 15 days. If it was not resolved during this period, it became a major deviation. Major deviations were documented on the form and had to be resolved within a month. The QA Coordinator evaluated whether corrective action had been performed. If it had not, the section director was sent a form with the major deviations noted. If it was still unresolved after another month, the QA Coordinator communicated the deviations to the NRL Director.

External check samples were analyzed every two years for each method/matrix for which the laboratory was accredited. The Program Leader was responsible for managing the preparation and evaluation of internal blind samples at the rate of 5% for methods with a small number of analyses per year or 6 to 10 blinds per year for methods with larger sample loads.

Several Analytical Methods were reviewed. They were:

Sulfonamides are analyzed using a TLC screen followed by HPLC-DAD . The method is quantitative and enforced at an MRL of 100 ppb. Only three sulfa drugs are included in the accredited method (sulfadiazine, sulfadoxine, and sulfadimidine), and action appears only to be taken on these three drugs. The laboratory does have information on additional sulfa drugs, but does not appear to do anything with that information. Their recoveries are listed as greater than 55% for the method. FSIS recoveries generally are 95 to 105%, using an internal standard.

The laboratory does participate in an interlaboratory comparison/proficiency program. That program, however, utilizes an unknown solution rather than a fortified sample.

Two positives were found last year from a total of about 100 samples.

Chloramphenicol is analyzed by GC/MS NCI in cattle, swine, fish, and poultry. The LOD's are 0.75 ppb for the first three, and 0.5 ppb for poultry muscle). The supervisor only reviews positive samples. A signature appears only on the LIMS, not on the hard copy. Confirmation criteria are based on 4 ions (two of them have a relative abundance of less than 5 % of the base peak!). A QC sample was integrated during the audit. One of the smaller ions was lost in the noise even though the other peaks were present. Several recent sample

data packages were examined. One positive sample for chloramphenicol was confirmed using the current (EC 96/253) criteria. Several data transcription errors were found in the data used to support another positive finding for chloramphenicol. Correcting the transcription error did not change the conclusion that chloramphenicol was confirmed.

Appendix D

Audit of the University of Gent Laboratory

Laboratory: Faculty Veterinary Medicine/Veterinary Food Inspection
Director: De Brabander
Status: EN 45001 Accredited

This university-based laboratory has a scientific staff that is divided into 3 units: Sample Preparation Unit (4); LC/MS^n Unit (3), and GC/MS Unit (2). The laboratory conducts research focussing on the development of new analytical methods and on other food quality issues. It also performs regulatory analyses under contract to the Ministry of Public Health. This laboratory is highly computerized, and uses "PC Anywhere," a software package that enables sample analyses from both the gc/ms and lc/ms/ms instruments to be monitored from home-based personal computers.

This laboratory has maximized its use of SOP's and has tried to use them to reduce the documentation that supports individual analyses. They have been reasonably successful in doing this although some problems are noted below.

The emphasis of this laboratory appears to be on being as efficient as possible in analyzing as many samples as possible and for the lowest cost in order to stay within fees the laboratory receives. This is not stated as a criticism as sample analysis efficiency and productivity are important aspects of laboratory management; rather it is a complement.

Each standard, spike or stock solution was identified by a unique number for that type of solution and its preparation was described in an SOP. The date of preparation, pH, etc., were entered on a solution's label which was not retained as part of permanent records. There were no permanent entries to document the preparation of standards, spikes or stock solutions to identify who prepared a specific solution, when it was prepared, whether the pH needed to be adjusted, etc. Consequently, standard and spike solutions used for a specific analysis could not be not traced. The presumption was that the last solution prepared was the one used for an analysis. Whether such traceability is required by BELTEST's guidance is dependent upon interpretation of sections 5.3.3/6 and 7 and 5.4.1/1.

Some solvents were labeled while others were not. The label did contain the date of receipt and each solvent had a unique identifying number. There were no records or notes that documented the manufacturer and lot of the solvents used in an analysis. Purchasing records were retained in the locked archives. Purchases were made whenever laboratory personnel noticed that the laboratory was running low on solvents.

In reviewing the LC-MS methods, documentation was distributed (scattered) in a number of notebooks. That is, information for a single sample could be found in the sample log book, in the analyst's daily log (which contained information on when samples were analyzed by LC-MS and the sequence of analysis), and also a logbook which identified individual MS files that were related to specific samples. Mass spectra were retained on compact disks.

Only hard copies of spectra for positive (violative) samples were retained in the archives. To find a mass spectrum for a specific sample which was not positive required consulting the sample log to obtain the laboratory's sample number, and the notebook on MS files for the spectrum's number, then the analyst's daily log to find the associated QC samples. Finally the spectrum could be found on the appropriate compact disk.

The disks were retained in the laboratory for approximately a year. When asked to find the results for a specific sample, the analyst could not find it until she remembered that the sample was analyzed on an older instrument and the spectra was on another series of CDs. Since it would have been difficult to find all of the documentation for a specific sample, the recommendation is made to develop an SOP which describes the manner in which information and records are retained (for instance, what information was entered in which notebook, where the information may be found, and similar information).

The laboratory's focus was on analysis of prohibited substances and it is accredited for qualitative analyses of these substances. For those analytes with MRL's, the laboratory screened samples to determine which were to be sent to another laboratory to determine whether levels were above the MRL. The laboratory did not have criteria for this determination. It was left up to the analyst's judgement. The recommendation is made to develop specific written criteria.

The laboratory archived hard copies of the mass spectra, reports, and inspectors' sample custody forms for positive results only. To adequately review these results however, quality control information also had to be reviewed, particularly for compounds with MRL's. This data is kept separately. The recommendation is made to archive all results, notebooks, and CDs.

The QA coordinator was not available. The auditors were told by the senior analyst that the QA Coordinator keeps files of calibrations, quality control results, audits, performance on blind samples, training records, SOP's, the QA Manual, records of monitoring freezer temperatures, minutes of monthly meetings, and complaints. The complaints included any problem with the samples or analyses. Our understanding was that files pertaining to the sample problems were not archived. Complaints were discussed in a monthly meeting between the QA Coordinator, Dr. De Brabander, and staff. Because information on the condition of a sample upon receipt was kept with the QA Coordinator, a review of the information on a sample would not have detected any problems. It is recommended that such information be kept in the sample log notebook and in the archived sample files.

Other aspects of sample custody and analysis could be improved. The laboratory did have limited access and a sign-in and out procedure for visitors that was enforced. Specific areas where samples were stored is not well documented. A recommendation is made to lock the sample freezer located in the hallway.

Data corrections were being improperly made in the sample receipt book (whiteout was used rather than drawing through the incorrect information then making the correction and initialing that correction).

Only one spiked sample and one tissue blank are analyzed with each batch of samples. For example, the analyst displayed a batch of 60 samples, analyzed over approximately two days (40+ hour run times), for which there was only one spiked sample. This level of quality control is well below appropriate standards. This is mitigated, in part, because of the inclusion of an internal standard in each analyzed sample. An unknown sample ("Q") sample is analyzed only once a month.

A sample was found to be positive (sum of the 7 PCBs exceeded 200 ppb) for PCB's in animal fat during the audit. The analyst is required to analyze quantitative recovery curves for the 7 PCBs monthly (minimum). A logbook of the curves is not maintained. The curve is validated with each batch by analyzing a recovery standard (80 - 120 % recovery). Results for the positive sample were calculated using a standard curve older than thirty days (in contradiction to the SOP) and the dates of standard curve analysis were not present on the spreadsheet.

Supervisory review appears to be limited to positive samples, rather than of all samples, and the record of that supervisory data review appears on the electronic report only. Only reports of positive results are printed; all negative analyses are stored electronically.

Problems related to sample analysis were listed on Sample Form. None were listed in the Sample Receipt Book, i.e., wrong sample, wrong tissue, missing sample, etc. There should be some traceability with information listed on the form and the sample receipt log.

Sample results that were positive were highlighted, providing everyone with good visual information on positive or violative results.

Equipment logs were very well kept. Each instrument had a number and corresponded to their logbook.

There were no calculations recorded in a book when standard solutions or reagents (pH buffers, 0.1000M NaOH.) were made. The laboratory staff started off with a "recipe" (an SOP), and ended with the final answer, but there were no calculations to see how they arrived at the final answer. Were there dilutions? Were some amounts "tweaked" to arrive at the answer? There was no traceability as to what balance or pH meter was used to measure the solutions.

New standards are not checked against the old ones. Doing this would allow analysts to check a new standard against an unexpired one and thereby verify results.

The laboratory had a well-developed computer system. All the SOP's were listed and available on the computer. However, they could not find an SOP on writing SOP's. There was an extensive listing (table of contents) of SOP's but some revision numbers were not current. There were a few entries that had one or two revision numbers lower than those in the SOP. This shows the table of contents is not always updated when new SOP's are updated.

The person who routinely performs a particular analysis approves the “Phase 4” results (the blind samples – unknown) obtained by a new analyst. The supervisor or equivalent should perform this. For an analyst to become “qualified” for an extraction procedure, six batches of samples have to be extracted on different days. In addition 10 series of samples have to be analyzed and assessed for the interpretation of the raw data. However, there should be a written SOP for this activity.

Laboratory methods for Anabolics, Corticosteroids, and PCB’s were closely reviewed. SOP's were available. The methods were properly run by the analysts, and samples reported to be positive could be tracked into the archives and data packages retrieved.

Although a number of problems and errors were uncovered, they can almost all be categorized as being small. The laboratory, in general, was well and efficiently run.

Appendix E

Visit to the Ministry of Agriculture Laboratory

Laboratory: DG4 – State Analysis Laboratory
Director: Courtheyn
Status: EN 45001 Accredited

A very limited amount of time was available in this laboratory. Because of this time constraint, the auditors did not consider their time there as an audit. The auditors were provided with a brief overview of the laboratory and the types of sample analyses it conducts.

This laboratory analyzes approximately 20,000 samples per year with a technical staff of nineteen. The staff also does research on development of new methods and new approaches to sample clean up in addition to the regulatory analyses. The staff had similar academic credentials (4 engineers, 5 industrial engineers, 8 chemists, and 2 technicians) to the other two laboratories. The analyses auditors were interested in (hormones, corticosteroids, β-agonists) are conducted on samples from live animals (urine and feces). The laboratory also analyzes animal feed (PCB's) as well as other food stuffs for trace levels of pesticides (e.g., chlormethquat in pears). A full complement of modern analytical instrumentation (hplc, lc/ms and gc/ms, ms/ms, etc) was available.

The laboratory was set up to operate in a "modular" approach. Each method was composed of a number of SOP's:(sample preparation; extraction; purification; screening; and confirmation). The modular approach enables the laboratory to change parts of methods with a minimum of training of analysts.

The laboratory tries to be as efficient as possible to keep its costs down. It had been automating sample preparation. Laboratory personnel tried to document each aspect of an analysis, however, shortcuts were observed. For instance, records stated that a Gilson was used to clean up a sample, however, the laboratory owned three Gilsons and there was no reference as to which one was used for a particular analysis.

Labeling of reagents and equipment was occasionally incomplete or missing. For example, several reagent bottles lacked labels and the laboratory had two Polaris GC's (one upstairs and one main level) that were not uniquely identified (other than by their location).

It appeared that analysts sometimes "checked" their own data without a higher level supervisor verifying the correctness of the data being reported out.

Auditors were unable to draw many conclusions concerning this laboratory, although the laboratory does appear to function quite effectively and does not have major, observable problems.